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09/550,605	04/17/2000	Leif Andersson	064727.0109	1231

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[REDACTED] EXAMINER

SOUAYA, JEHANNE E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1634

DATE MAILED: 04/09/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/550,605

Applicant(s)

Andersson et al

Examiner

Jehanne Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 7, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-17 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-17 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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DETAILED ACTION

1. Currently, claims 1-17 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied (necessitated by amendment) or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The preliminary amendment filed 1/29/2001 has been received and the appropriate corrections have been made. The preliminary amendment was not acknowledged in the previous office action as the amendment had not been matched with the case prior to the previous office action. In view of the preliminary amendment, the rejection under 35 USC 112/2nd paragraph, for claims 3, 5, and 14 is moot. Further, the rejection under 35 USC 112/2nd paragraph for claims 1 and 14 lacking a positive process step has been rendered moot due to the amendment filed August 13, 2001.

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4. With regard to the issues raised in the previous office action regarding the sequence listing, it is noted that pages 4, 17-20 and 29 of the specification and the claims contain sequences not designated by a proper sequence identifier. Applicants corrected disk was received and entered.

Maintained Rejections

Written Description

5. Claims 1,4,5,8,10-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to determining coat color genotype in a pig comprising analyzing a nucleic acid sample to determine whether a mutation is or is not present at an exon 17/intron splice site of the KIT gene (claims 1,4,5,8 and 10-13), or whether a splice variant protein is present (claim 14). The specification teaches that an alteration of the 5' intron splice site of intron 17 of the KIT2 gene is associated with the white coat color of pigs. The specification teaches that the alteration is from a GT pair to an AT pair which affects the splicing of the pre mRNA and results in the loss of the whole of exon 17 from the mRNA transcribed from the I-KIT2 sequence. The specification fails to describe a representative number of the various substitutions, insertions, deletions or frame shift mutations that are encompassed by the claims on either side of exon17. Furthermore, applicants have only taught one splice variant protein that

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would result from a single mutation. Each of the claimed inventions is a genus for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description much convey to one of skill in the art “with reasonable clarity” that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of genotypes corresponding to any mutation at exon17/intron splice site of the KIT gene and how these effect the coat color of a pig, the specification fails to show that applicant was in fact, “in possession of the claimed invention” at the time the application for patent was filed.

Response to Arguments

The response asserts that the examiner acknowledges that the specification discloses an alteration in the splice site of intron 17 which is associated with a specific coat color and that the amendment to the claims places the application in condition for allowance. The amendments and applicants comments have been thoroughly reviewed but were not found persuasive and are insufficient to place the application in condition for allowance. The claims not only still recite any mutation but they also recite exon17/intron which encompasses the splice site at intron16/exon17. As the specification only teaches of a single mutation, substitution of the G of the conserved GT pair for A at the exon17/intron17 boundary which results in a protein lacking all of exon 17, the specification fails to provide a representative number of species of mutations

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that would correlate with a specific coat color in a pig. The claims encompass methods and kits for detecting any mutation at exon17/intron splice site and correlating these mutations with the coat color in a pig, however the specification does not teach a predictable correlation with any of these mutations and a specific coat color in a pig. Without such teaching, the skilled artisan would not be able to envision the number of different mutations in an exon17/intron splice site that would be correlated with a specific coat color in a pig.

Indefinite

6. Claims 1-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 15 are indefinite as it is unclear which side of an intron is encompassed by the language “exon17/intron splice site”. For example, does this refer to the boundary of exon 17 and intron 17, or does it also include the boundary of intron 16 and exon 17 (3' of intron).

Response to Arguments

The response does not address this rejection.

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New Grounds of Rejection

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moller et al., (Mammalian Genome, 1996, vol. 7, pp 822-830) in view of Ahern ("Biochemical Reagent Kits Offer Scientists Good Return on Investment", pp 1-5, from The Scientist, vol: 9, page 20, 1995).

Claims 15 and 16 are drawn to a kit comprising one or more reagents suitable for determining whether a mutation is present at an exon17/intron splice site of the KIT gene and reagents for carrying out a PCR reaction. Such a kit reads on nucleic acid primers that will amplify a fragment of the KIT gene at any exon17/intron boundary of the KIT gene. Moller (1996) teaches primers KIT1F and KIT1R that localize to exon 16 and exon 17 of the KIT gene. Such primers would amplify a fragment containing the intron16/exon17 splice site which is encompassed by the recitation of "exon17/intron" in the claim. It would have been obvious to package these primers in kit format for a PCR reaction, including reagents for PCR, as Ahern teaches that kits accelerate the research process, are convenient and save time (p. 4). As the use for a kit carries no patentable weight, such primers read on claim 15 and 16 regardless of why

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they were designed. It is further noted that any PCR kit, containing only reagents for PCR and not specific primers, or a kit containing only a restriction enzyme would read on claim 15 as the use for a kit carries no patentable weight.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method or kit for determining coat color genotype in a pig which comprises obtaining a sample for pig nucleic and analyzing the nucleic acid obtained to determine whether a substitution of the G of the conserved GT pair with A at the exon17/intron17 splice site of KIT-2 wherein presence or absence of said substitution is correlated with coat color or to a method for determining coat color genotype in a pig by analyzing a sample of pig KIT protein to determine whether a splice variant protein missing exon 17 is present, said splice variant protein missing exon 17 being correlated with coat color, does not reasonably provide enablement for a method for determining coat color genotype in a pig by determining whether 1) a mutation is or is not present at an exon17/intron splice site, or 2) any mutation is present at exon17/intron17 boundary of KIT gene, wherein presence or absence of the

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mutation is correlated with coat color or 3) any splice variant protein present being correlated with coat color. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to methods and kits for determining coat color genotype in a pig by determining whether a mutation is or is not present at an exon17/intron splice site, or any mutation is present at exon17/intron17 boundary of the KIT gene, wherein presence or absence of the mutation is correlated with coat color and to methods for determining coat color genotype in a pig by correlating any splice variant KIT protein with coat color. The specification teaches that the alteration is from a GT pair to an AT pair which affects the splicing of the pre mRNA and results in the loss of the whole of exon 17 from the mRNA transcribed from the I-KIT2 sequence. The specification does not teach correlating coat color to any of the various substitutions, insertions, deletions or frame shift mutations that are encompassed by the claims on either side of exon17 (it is noted that the claim recites “exon17/intron splice site” without indicating a specific intron on either side of exon 17). The specification does not teach what the coat color of a pig would be if only a single copy of the KIT gene is present and possesses the G to A substitution in the conserved GT pair. Further, conserved sequences important for proper splicing of introns are present at both the 5' end and the 3' end of an intron. The specification, however, does not teach of any mutations in the intron16/exon17 splice site that might affect

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splicing of exon 16, nor does the specification teach or suggest whether coat color would be affected by such a mutation.

The art does not teach of a correlation between mutations in the KIT gene and coat color of a pig. Since it is unclear from the teachings in the specification or the art as to how mutations in the KIT gene affect coat color in a pig, it is unpredictable as to whether the myriad of mutations in either one or a second or both copies of the KIT gene encompassed by the broadly claimed invention would affect coat color in a pig or how they would affect coat color in a pig. Neither the specification nor the art teach a predictable correlation between the large number of possible mutations in a single KIT gene, or the 2nd of two KIT genes, or 2 KIT genes encompassed by the claims and coat color in a pig. The specification only teaches of a single substitution from a G to an A in the conserved GT pair at the exon17/intron17 splice site in the second copy of KIT gene that results in a single splice variant KIT protein lacking exon 17 and results in a pig with white coat color. This single mutation is not sufficient to establish a predictable correlation for the skilled artisan between the large number of mutations encompassed by the claims and any coat color of a pig. As correlating a particular coat color with the large number of mutations in the KIT gene encompassed by the broadly claimed invention is unpredictable in light of the lack of teaching and guidance in the specification and the art, the skilled artisan would be required to perform undue experimentation to make or use the invention as broadly as it is claimed. While the amount of experimentation needed is not

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necessarily considered undue, such experimentation would be replete with trial and error, thus constituting undue experimentation.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claims are allowable.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634

4/3/02